IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| IN RE:<br><br>BRIMONIDINE PATENT LITIGATION | MDL Docket No. 07-md-01866 GMS |

**REVISED JOINT CLAIM CHARTS**

**'078 patent**[1][2]

| Asserted Claim of '078 patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| **Claim 1** | | |
| 1. A method for preserving an aqueous ophthalmic formulation so as to enhance the shelf life thereof comprising | Agreed-upon construction:<br>The claim requires a method for preserving an aqueous ophthalmic formulation to enhance the shelf life of the formulation. | |
| incorporating into said aqueous ophthalmic formulation stabilized chlorine dioxide in an amount effective to act as the sole preservative in said aqueous ophthalmic formulation, | Agreed-upon construction:<br>The claimed method requires incorporation into the aqueous ophthalmic formulation of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the formulation. | |
| at least one ophthalmically acceptable buffer component in an amount effective to maintain said aqueous ophthalmic formulation at a pH in the range of about 6.8 to about 8, | Agreed-upon construction:<br>The claimed method requires incorporation into the aqueous ophthalmic formulation of at least one ophthalmically acceptable buffer component in an amount effective to maintain the formulation at a pH in the range of approximately 6.8 to approximately 8. | |
| and at least one ophthalmically acceptable | Agreed-upon construction:<br>The claimed method requires incorporation into the aqueous | |

1 Allergan and Apotex agree on the construction of all claim terms of the '078 patent.
2 Allergan and Apotex agree the ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).

| Asserted Claim of '078 patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| tonicity component in an amount effective to maintain said aqueous ophthalmic formulation at an osmolality of at least about 200 mOsmol/kg, | ophthalmic formulation of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the formulation at an osmolality of at least approximately 200 mOsmol/kg. | |
| provided that said aqueous ophthalmic formulation is ophthalmically acceptable and no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers are incorporated into said aqueous ophthalmic formulation. | Agreed-upon construction:<br>The claimed method requires that the aqueous ophthalmic formulation is ophthalmically acceptable and that it includes no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers. | |
| **Claim 2** | | |
| 2. The method of claim 1 wherein said stabilized chlorine dioxide is present in said aqueous ophthalmic formulation in an amount in the range of about 0.0002 to about 0.02 weight/volume percent. | Agreed-upon construction:<br>Claim 2 contains all the limitations of claim 1, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.0002 to approximately 0.02 weight/volume percent. | |
| **Claim 3** | | |
| 3. The method of claim 1 wherein said stabilized chlorine dioxide is present in said aqueous ophthalmic formulation in an amount in the range of about 0.004 to about 0.01 weight/volume percent. | Agreed-upon construction:<br>Claim 3 includes all the limitations of claim 1, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.004 to approximately 0.01 weight/volume percent. | |
| **Claim 4** | | |
| 4. The method of claim 1 wherein said at least one ophthalmically acceptable buffer component is present in an amount effective to maintain said aqueous ophthalmic formulation at a pH in the range of about 7 to about 7.5. | Agreed-upon construction:<br>Claim 4 includes all the limitations of claim 1, with the further requirement that at least one ophthalmically acceptable buffer component is present in an amount effective to maintain the formulation at a pH in the range of approximately 7 to approximately 7.5. | |

| Asserted Claim of '078 patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| **Claim 5** | | |
| 5. The method of claim 1 wherein said at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain said aqueous ophthalmic formulation at an osmolality in the range of about 200 to about 400 mOsmol/kg. | Agreed-upon construction:<br>Claim 5 includes all the limitations of claim 1, with the further requirement that at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain the formulation at an osmolality in the range of approximately 200 to approximately 400 mOsmol/kg. | |
| **Claim 6** | | |
| 6. The method of claim 1 wherein said aqueous ophthalmic formulation is a solution. | Agreed-upon construction:<br>Claim 6 includes all the limitations of claim 1 with the further requirement that the aqueous ophthalmic formulation is a solution. | |
| **Claim 7** | | |
| 7. A method for preserving an aqueous ophthalmic solution so as to enhance the shelf life thereof comprising | Agreed-upon construction:<br>The claim requires a method for preserving an aqueous ophthalmic solution to enhance the shelf life of the solution. | |
| incorporating into said aqueous ophthalmic solution stabilized chlorine dioxide in an amount effective to act as the sole preservative in said aqueous ophthalmic solution in the range of about 0.002 to about 0.02 weight/volume percent, | Agreed-upon construction:<br>The claimed method requires incorporation into the aqueous ophthalmic solution of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the solution in the range of approximately 0.0002 to approximately 0.02 weight/volume percent. | |
| at least one ophthalmically acceptable buffer component in an amount effective to maintain said aqueous ophthalmic solution at a pH in the range of about 6.8 to about 8, | Agreed-upon construction:<br>The claimed method requires incorporation into the aqueous ophthalmic solution of at least one ophthalmically acceptable buffer component in an amount effective to maintain the solution at a pH in the range of approximately 6.8 to approximately 8. | |
| and at least one ophthalmically acceptable tonicity component in an amount effective to maintain said aqueous ophthalmic solution at an osmolality in the range of about 200 to | Agreed-upon construction:<br>The claimed method requires incorporation into the aqueous ophthalmic solution of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the solution at an osmolality in the range of approximately 200 mOsmol/kg to approximately 400 mOsmol/kg. | |

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| about 400 mOsmol/kg, | | |
| provided that said aqueous ophthalmic solution is ophthalmically acceptable and substantially no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers are incorporated into said aqueous ophthalmic solution. | Agreed-upon construction:<br>The claimed method requires that the aqueous ophthalmic solution is ophthalmically acceptable and that it includes substantially no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers. | |
| **Claim 8** | | |
| 8. A preserved ophthalmic formulation comprising | Agreed-upon construction:<br>The claim requires a preserved ophthalmic formulation. | |
| an ophthalmically acceptable aqueous medium and, | Agreed-upon construction:<br>The claimed formulation requires an ophthalmically acceptable aqueous medium. | |
| included therein, stabilized chlorine dioxide in an amount effective to act as the sole preservative in said ophthalmically acceptable aqueous medium, | Agreed-upon construction:<br>The claimed formulation requires the inclusion of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the ophthalmically acceptable aqueous medium. | |
| at least one ophthalmically acceptable buffer component in an amount effective to maintain said ophthalmically acceptable aqueous medium at a pH in the range of about 6.8 to about 8, | Agreed-upon construction:<br>The claimed formulation requires the inclusion of at least one ophthalmically acceptable buffer component in an amount effective to maintain the ophthalmically acceptable aqueous medium at a pH in the range of approximately 6.8 to approximately 8. | |
| and at least one ophthalmically acceptable tonicity component in an amount effective to maintain said ophthalmically acceptable aqueous medium at an osmolality of at least about 200 mOsmol/kg, | Agreed-upon construction:<br>The claimed formulation requires the inclusion of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the ophthalmically acceptable aqueous medium at an osmolality of at least approximately 200 mOsmol/kg. | |
| provided that said preserved ophthalmic formulation is ophthalmically acceptable and is free of germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers. | Agreed-upon construction:<br>The claimed formulation is ophthalmically acceptable and free of germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers. | |

| Asserted Claim of '078 patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| **Claim 9** | | |
| 9. The preserved ophthalmic formulation of claim 8 wherein said stabilized chlorine dioxide is present in said preserved ophthalmic formulation in an amount in the range of about 0.0002 to about 0.02 weight/volume percent. | Agreed-upon construction:<br>Claim 9 contains all the limitations of claim 8, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.0002 to approximately 0.02 weight/volume percent. | |
| **Claim 10** | | |
| 10. The preserved ophthalmic formulation of claim 8 wherein said stabilized chlorine dioxide is present in said preserved ophthalmic formulation in an amount in the range of about 0.004 to about 0.01 weight/volume percent. | Agreed-upon construction:<br>Claim 10 contains all the limitations of claim 8, with the further requirement that the stabilized chlorine dioxide is present in the formulation in an amount in the range of approximately 0.004 to approximately 0.01 weight/volume percent. | |
| **Claim 11** | | |
| 11. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component is selected from the group consisting of alkali metal chlorides and alkaline earth metal chlorides and mixtures thereof. | Agreed-upon construction:<br>Claim 11 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component is selected from the group consisting of alkali metal chlorides and alkaline earth metal chlorides and mixtures thereof. | |
| **Claim 12** | | |
| 12. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component comprises sodium chloride. | Agreed-upon construction:<br>Claim 12 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component comprises sodium chloride. | |
| **Claim 13** | | |
| 13. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component comprises an alkaline earth metal salt | Agreed-upon construction:<br>Claim 13 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component comprises an alkaline earth metal salt selected from the group consisting of calcium chloride and magnesium chloride and mixtures thereof. | |

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| selected from the group consisting of calcium chloride and magnesium chloride and mixtures thereof. | | |
| **Claim 14** | | |
| 14. The preserved ophthalmic formulation of claim 8 wherein said at least one buffer component is selected from the group consisting of potassium phosphates, boric acid, sodium borate, sodium phosphates and mixtures thereof. | Agreed-upon construction:<br>Claim 14 contains all the limitations of claim 8, with the further requirement that at least one buffer component is selected from the group consisting of potassium phosphates, boric acid, sodium borate, sodium phosphates and mixtures thereof. | |
| **Claim 15** | | |
| 15. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable buffer component is present in an amount effective to maintain said ophthalmically acceptable aqueous medium at a pH in the range of about 7 to about 7.5. | Agreed-upon construction:<br>Claim 15 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable buffer component is present in an amount effective to maintain the ophthalmically acceptable aqueous medium at a pH in the range of approximately 7 to approximately 7.5. | |
| **Claim 16** | | |
| 16. The preserved ophthalmic formulation of claim 8 wherein said at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain said ophthalmically acceptable aqueous medium at an osmolality in the range of about 200 to about 400 mOsmol/kg. | Agreed-upon construction:<br>Claim 16 contains all the limitations of claim 8, with the further requirement that at least one ophthalmically acceptable tonicity component is present in an amount effective to maintain the ophthalmically acceptable aqueous medium at an osmolality in the range of approximately 200 to approximately 400 mOsmol/kg. | |
| **Claim 17** | | |
| 17. The preserved ophthalmic formulation of claim 8 which is a solution. | Agreed-upon construction:<br>Claim 17 contains all the limitations of claim 8, with the further requirement that the formulation is a solution. | |
| **Claim 18** | | |
| 18. A preserved ophthalmic solution comprising | Agreed-upon construction:<br>The claim requires a preserved ophthalmic solution. | |

| Asserted Claim of '078 patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| an ophthalmically acceptable aqueous solution and, | Agreed-upon construction:<br>The claim requires an ophthalmically acceptable aqueous solution. | |
| included therein, stabilized chlorine dioxide in an amount effective to act as the sole preservative in said ophthalmically aqueous acceptable solution in the range of about 0.002 to about 0.02 weight/volume percent, | Agreed-upon construction:<br>The claimed solution requires the inclusion of stabilized chlorine dioxide in an amount effective to act as the sole preservative in the ophthalmically acceptable aqueous solution in the range of approximately 0.002 to approximately 0.02 weight/volume percent. | |
| at least one ophthalmically acceptable buffer component in an amount effective to maintain said ophthalmically acceptable aqueous solution at a pH in the range of about 6.8 to about 8, | Agreed-upon construction:<br>The claimed solution requires the inclusion of at least one ophthalmically acceptable buffer component in an amount effective to maintain the ophthalmically acceptable aqueous solution at a pH in the range of approximately 6.8 to approximately 8. | |
| and at least one ophthalmically acceptable tonicity component in an amount effective to maintain said ophthalmically acceptable aqueous solution at an osmolality in the range of about 200 to about 400 mOsmol/kg, | Agreed-upon construction:<br>The claimed solution requires the inclusion of at least one ophthalmically acceptable tonicity component in an amount effective to maintain the ophthalmically acceptable aqueous solution at an osmolality in the range of approximately 200 mOsmol/kg to approximately 400 mOsmol/kg. | |
| provided that said preserved ophthalmic solution is ophthalmically acceptable and is free of germicidally effective amounts of any positively charged, nitrogen-containing polymers. | Agreed-upon construction:<br>The claimed solution is ophthalmically acceptable and free of germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers. | |

**'873 patent**[3]

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| **Claim 1.** | | |
| 1. A composition comprising: | | |
| a therapeutically active component selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof, and being present in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered; | Agreed-upon construction:<br>The claimed composition contains a component selected from the group consisting of an alpha-2-adrenergic agonist and mixtures thereof, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient to whom the composition is administered. | |
| a solubility enhancing component, other than a cyclodextrin, in an amount effective to increase the solubility of the therapeutically active component in the composition relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component; | Agreed-upon construction:<br>The claimed composition contains an amount of a solubility enhancing component, which is a component other than a cylclodextrin that solubilizes more of the therapeutically active component relative to a similar composition without the solubility enhancing component. | |
| an oxy-chloro component in an effective amount to at least aid in preserving the composition; | Agreed-upon construction:<br>The claimed composition contains an oxy-chloro component in an effective amount to at least aid in preserving the composition | |
| and a liquid carrier component. | Agreed-upon construction:<br>The claimed composition contains a liquid carrier component. | |
| **Claim 2.** | | |
| 2. The composition of claim 1 wherein the therapeutically active component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, | Agreed-upon construction:<br>Claim 2 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, and mixtures thereof. | |

[3] Allergan and Apotex agree on the construction of all claim terms of the '873 patent.

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| catecholamines, and mixtures thereof. | | |
| **Claim 3.** | | |
| 3. The composition of claim 1 wherein the therapeutically active component includes a quinoxaline component. | Agreed-upon construction:<br>Claim 3 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component includes a quinoxaline component. | |
| **Claim 4.** | | |
| 4. The composition of claim 3 wherein the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof. | Agreed-upon construction:<br>Claim 4 includes all of the limitations of claim 3, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof. | |
| **Claim 5.** | | |
| 5. The composition of claim 3 wherein the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and mixtures thereof. | Agreed-upon construction:<br>Claim 5 includes all of the limitations of claim 3, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, brimonidine, and brimonidine tartrate, and mixtures thereof. | |
| **Claim 6.** | | |
| 6. The composition of claim 1 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline. | Agreed-upon construction:<br>Claim 6 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component comprises brimonidine tartrate. | |
| **Claim 7.** | | |
| 7. The composition of claim 1 wherein the therapeutically active component has increased diffusion through a lipid membrane relative to an identical therapeutically active component in a similar composition without the | Agreed-upon construction:<br>Claim 7 includes all of the limitations of claim 1, with the further requirement that the therapeutically active component has increased diffusion through a lipid membrane relative to an identical therapeutically active component in a similar composition without the solubility enhancing component. | |

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| solubility enhancing component. | | |
| **Claim 8.** | | |
| 8. The composition of claim 1 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the therapeutically active component relative to the solubility in a biological environment of an identical therapeutically active component in a similar composition without the solubility enhancing component. | Agreed-upon construction:<br>Claim 8 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is effective to solubilize more in a biological environment of the therapeutically active component relative to the solubility in a biological environment of an identical therapeutically active component in a similar composition without the solubility enhancing component. | |
| **Claim 9.** | | |
| 9. The composition of claim 1 wherein the solubility enhancing component comprises a polyanionic component. | Agreed-upon construction:<br>Claim 9 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component comprises a polyanionic component. | |
| **Claim 10.** | | |
| 10. The composition of claim 9 wherein said polyanionic components is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic acid, anionic polymers derived from amino acids and mixtures thereof. | Agreed-upon construction:<br>Claim 10 includes all of the limitations of claim 9, with the further requirement that the said polyanionic component is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic acid, anionic polymers derived from amino acids and mixtures thereof. | |
| **Claim 11.** | | |
| 11. The composition of claim 1 wherein the solubility enhancing component comprises an anionic cellulose derivative. | Agreed-upon construction:<br>Claim 11 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component comprises an anionic cellulose derivative. | |

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| **Claim 12.** | | |
| 12. The composition of claim 1 wherein the solubility enhancing component comprises a carboxymethylcellulose. | Agreed-upon construction:<br>Claim 12 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component comprises a carboxymethylcellulose. | |
| **Claim 13.** | | |
| 13. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.1% (w/v) to about 30% (w/v). | Agreed-upon construction:<br>Claim 13 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is present in an amount in a range of approximately 0.1% (w/v) to approximately 30% (w/v). | |
| **Claim 14.** | | |
| 14. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 10 (w/v). | Agreed-upon construction:<br>Claim 14 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is present in an amount in a range of approximately 0.2% (w/v) to approximately 10 (w/v). | |
| **Claim 15.** | | |
| 15. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v). | Agreed-upon construction:<br>Claim 15 includes all of the limitations of claim 1, with the further requirement that the solubility enhancing component is present in an amount in a range of approximately 0.2% (w/v) to approximately 0.6% (w/v). | |
| **Claim 16.** | | |
| 16. The composition of claim 1 wherein the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof. | Agreed-upon construction:<br>Claim 16 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof. | |
| **Claim 17.** | | |
| 17. The composition of claim 1 wherein the oxy-chloro component comprises a chlorite component. | Agreed-upon construction:<br>Claim 17 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component comprises a chlorite component. | |
| **Claim 18.** | | |
| 18. The composition of claim 1 wherein the oxy-chloro | Agreed-upon construction:<br>Claim 18 includes all of the limitations of claim 1, with the | |

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| component comprises stabilized chlorine dioxide. | further requirement that the oxy-chloro component comprises stabilized chlorine dioxide. | |
| **Claim 19.** | | |
| 19. The composition of claim 1, wherein the oxy-chloro component is present in an amount of about 500 ppm (w/v) or less. | Agreed-upon construction:<br>Claim 19 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component is present in an amount of approximately 500 ppm (w/v) or less. | |
| **Claim 20.** | | |
| 20. The composition of claim 1 wherein the oxy-chloro component is present in an amount in a range of about 10 ppm (w/v) to about 200 ppm (w/v). | Agreed-upon construction:<br>Claim 20 includes all of the limitations of claim 1, with the further requirement that the oxy-chloro component is present in an amount in a range of approximately 10 ppm (w/v) to approximately 200 ppm (w/v). | |
| **Claim 23.** | | |
| 23. The composition of claim 1 wherein the liquid carrier is an aqueous liquid carrier component. | Agreed-upon construction:<br>Claim 23 includes all of the limitations of claim 1, with the further requirement that the liquid carrier is an aqueous liquid carrier component. | |
| **Claim 24.** | | |
| 24. The composition of claim 1 which is a solution. | Agreed-upon construction:<br>Claim 24 includes all of the limitations of claim 1, with the further requirement that the composition of claim 1 is a solution. | |
| **Claim 25.** | | |
| 25. The composition of claim 1 which has a pH of about 7 or greater. | Agreed-upon construction:<br>Claim 25 includes all of the limitations of claim 1, with the further requirement that has a pH of approximately 7 or greater. | |
| **Claim 26.** | | |
| 26. The composition of claim 1 which has a pH in a range of about 7 to about 9. | Agreed-upon construction:<br>Claim 26 includes all of the limitations of claim 1, with the further requirement that the composition has a pH in a range of approximately 7 to approximately 9. | |
| **Claim 27.** | | |
| 27. The composition of claim 1 which is ophthalmically acceptable. | Agreed-upon construction:<br>Claim 27 includes all of the limitations of claim 1, with the further requirement that the composition is ophthalmically acceptable. | |
| **Claim 28.** | | |
| 28. A composition comprising: | | |
| a therapeutically active component selected from the | Agreed-upon construction:<br>The claimed composition contains a therapeutically active | |

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| group consisting of alpha-2-adrenergic agonists and mixtures thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered; | component selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered. | |
| an anionic cellulose derivative in an amount effective to increase the solubility of the therapeutically active component; | Agreed-upon construction:<br>The claimed composition contains an anionic cellulose derivative in an amount effective to solubilize more of the therapeutically active component. | |
| a chlorite component in an effective amount to at least aid in preserving the composition; | Agreed-upon construction:<br>The claimed composition contains a chlorite component in an effective amount to at least aid in preserving the composition | |
| and an aqueous liquid carrier component. | Agreed-upon construction:<br>The claimed composition contains an aqueous liquid carrier component. | |
| **Claim 29.** | | |
| 29. The composition of claim 28 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline. | Agreed-upon construction:<br>Claim 29 includes all of the limitations of claim 28, with the further requirement that the therapeutically active component comprises brimonidine tartrate. | |
| **Claim 30.** | | |
| 30. The composition of claim 28 wherein the anionic cellulose derivative comprises carboxymethylcellulose. | Agreed-upon construction:<br>Claim 30 includes all of the limitations of claim 28, with the further requirement that the anionic cellulose derivative comprises carboxymethylcellulose. | |
| **Claim 31.** | | |
| 31. The composition of claim 28 wherein the anionic cellulose derivative is present in an amount in a range of about 0.2% to about 0.6% (w/v). | Agreed-upon construction:<br>Claim 31 includes all of the limitations of claim 28, with the further requirement that the anionic cellulose derivative is present in an amount in a range of approximately 0.2% to approximately 0.6% (w/v). | |
| **Claim 32.** | | |
| 32. A composition comprising: | | |
| a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline in an amount | Agreed-upon construction:<br>The claimed composition contains brimonidine tartrate in an amount effective to provide a therapeutic benefit to a patient to | |

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| effective to provide a therapeutic benefit to a patient to whom the composition is administered; | whom the composition is administered. | |
| a solubility enhancing component in an amount effective to increase the solubility of the tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline; | Agreed-upon construction:<br>The claimed composition contains a solubility enhancing component in an amount effective to solubilize more of brimonidine tartrate. | |
| a chlorite component in an effective amount to at least aid in preserving the composition; | Agreed-upon construction:<br>The claimed composition contains a chlorite component in an effective amount to at least aid in preserving the composition. | |
| and an aqueous liquid carrier component. | Agreed-upon construction:<br>The claimed composition contains an aqueous liquid carrier component. | |
| **Claim 33.** | | |
| 33. The composition of claim 32 wherein the solubility enhancing component comprises a carboxymethylcellulose. | Agreed-upon construction:<br>Claim 33 includes all of the limitations of claim 32, with the further requirement that the solubility enhancing component comprises a carboxymethylcellulose. | |
| **Claim 34.** | | |
| 34. The composition of claim 32 which is ophthalmically acceptable. | Agreed-upon construction:<br>Claim 34 includes all of the limitations of claim 32, with the further requirement that the composition of claim 32 is ophthalmically acceptable. | |
| **Claim 35.** | | |
| 35. A composition comprising: | | |
| a therapeutically active component in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered; | Agreed-upon construction:<br>The claimed composition contains a therapeutically active component in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered. | |
| an oxy-chloro component in an effective amount to at least aid in preserving the composition; | Agreed-upon construction:<br>The claimed composition contains an oxy-chloro component in an effective amount to at least aid in preserving the composition. | |
| and a liquid carrier component, wherein the composition is substantially | Agreed-upon construction:<br>The claimed composition contains a liquid carrier component, wherein the composition is substantially free of cyclodextrins. | |

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
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| free of cyclodextrins. | | |
| **Claim 36.** | | |
| 36. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of antibacterials, antihistamines, decongestants, antiinflammatories, antiparasitics, miotics, anticholinergics, adrenergics, antivirals, local anesthetics, antifungals, amoebicidals, trichomonocidals, analgesics, mydriatics, antiglaucoma drugs, carbonic anhydrase inhibitors, ophthalmic diagnostic agents, ophthalmic agents used as adjuvants in surgery, chelating agents, antineoplascics, antihypertensives, muscle relaxants, diagnostics, and mixtures thereof. | Agreed-upon construction:<br>Claim 36 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of antibacterials, antihistamines, decongestants, antiinflammatories, antiparasitics, miotics, anticholinergics, adrenergics, antivirals, local anesthetics, antifungals, amoebicidals, trichomonocidals, analgesics, mydriatics, antiglaucoma drugs, carbonic anhydrase inhibitors, ophthalmic diagnostic agents, ophthalmic agents used as adjuvants in surgery, chelating agents, antineoplascics, antihypertensives, muscle relaxants, diagnostics, and mixtures thereof. | |
| **Claim 37.** | | |
| 37. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of adrenergic agonists and mixtures thereof. | Agreed-upon construction:<br>Claim 37 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of adrenergic agonists and mixtures thereof. | |
| **Claim 38.** | | |
| 38. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof. | Agreed-upon construction:<br>Claim 38 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of alpha-2-adrenergic agonists and mixtures thereof. | |
| **Claim 39.** | | |
| 39. The composition of claim 35 wherein the therapeutically active component is selected from the group consisting of imino-imidazolines, | Agreed-upon construction:<br>Claim 39 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, | |

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, and mixtures thereof. | guanidines, catecholamines, and mixtures thereof. | |
| **Claim 40.** | | |
| 40. The composition of claim 35 wherein the therapeutically active component includes a quinoxaline component. | Agreed-upon construction:<br>Claim 40 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component includes a quinoxaline component. | |
| **Claim 41.** | | |
| 41. The composition of claim 40 wherein the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof. | Agreed-upon construction:<br>Claim 41 includes all of the limitations of claim 40, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxalines, quinoxaline derivatives, and mixtures thereof. | |
| **Claim 42.** | | |
| 42. The composition of claim 40 wherein the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and mixtures thereof. | Agreed-upon construction:<br>Claim 42 includes all of the limitations of claim 40, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, brimonidine, and brimonidine tartrate, and mixtures thereof. | |
| **Claim 43.** | | |
| 43. The composition of claim 35 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline. | Agreed-upon construction:<br>Claim 43 includes all of the limitations of claim 35, with the further requirement that the therapeutically active component comprises brimonidine tartrate. | |
| **Claim 44.** | | |
| 44. The composition of claim 35, which further includes a solubility enhancing component, other than a cyclodextrin, in an amount | Agreed-upon construction:<br>Claim 44 includes all of the limitations of claim 35, with the further requirement that the composition of claim 35, further includes a solubility enhancing component, other than a cyclodextrin, in an amount effective to solubilize more of the | |

| Asserted Claim of '873 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| effective to increase the solubility of the therapeutically active component in the composition relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component. | therapeutically active component in the composition relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component. | |
| **Claim 45.** | | |
| 45. The composition of claim 44 wherein the solubility enhancing component comprises a polyanionic component. | Agreed-upon construction:<br>Claim 45 includes all of the limitations of claim 44, with the further requirement that the solubility enhancing component comprises a polyanionic component. | |
| **Claim 46.** | | |
| 46. The composition of claim 35 wherein the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof. | Agreed-upon construction:<br>Claim 46 includes all of the limitations of claim 35, with the further requirement that the oxy-chloro component is selected from the group consisting of hypochlorite components, perchlorate components, chlorite components and mixtures thereof. | |
| **Claim 47.** | | |
| 47. The composition of claim 35 wherein the oxy-chloro component comprises a chlorite component. | Agreed-upon construction:<br>Claim 47 includes all of the limitations of claim 35, with the further requirement that the oxy-chloro component comprises a chlorite component. | |
| **Claim 48.** | | |
| 48. The composition of claim 35 wherein the oxy-chloro component comprises stabilized chlorine dioxide. | Agreed-upon construction:<br>Claim 48 includes all of the limitations of claim 35, with the further requirement that the oxy-chloro component comprises stabilized chlorine dioxide. | |
| **Claim 49.** | | |
| 49. The composition of claim 35 which is ophthalmically acceptable. | Agreed-upon construction:<br>Claim 49 includes all of the limitations of claim 35, with the further requirement that the composition of claim 35 is ophthalmically acceptable. | |

**'210 patent**[4]

| Asserted Claim of '210 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| **Claim 1** | | |
| 1. A therapeutically effective aqueous composition comprising: | Agreed-upon construction:<br>The claim requires a therapeutically effective aqueous composition. | |
| a therapeutically active alpha-2-adrenergic agonist component selected from the group consisting of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, a salt thereof, and an ester thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered; | Agreed-upon construction:<br>The claimed composition comprises a therapeutically active alpha-2-adrenergic agonist component, and that component is selected from the group consisting of brimonidine, salts of brimonidine, or esters of brimonidine, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient. | |
| and a polyanionic solubility enhancing component in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component. | Agreed-upon construction:<br>The claimed composition comprises a polyanionic solubility enhancing component, which is a component that enhances the solubility of the alpha-2-adrenergic agonist component. The solubility enhancing component is present in such an amount that more of the alpha-2-adrenergic agonist component is solubilized in the composition relative to a similar composition without the solubility enhancing component. | |
| **Claim 2** | | |
| 2. The composition of claim 1 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline. | Agreed-upon construction:<br>Claim 2 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component comprises brimonidine tartrate. | |
| **Claim 3** | | |
| 3. The composition of claim 1 wherein the therapeutically active component is substantially unionized. | Agreed-upon construction:<br>Claim 3 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component is substantially unionized. | |
| **Claim 4** | | |

[4] Allergan and Apotex agree on the construction of all claim terms of the '210 patent.

| Asserted Claim of '210 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| 4. The composition of claim 1 wherein the therapeutically active component is substantially unionized in a biological environment to which the composition is administered. | Agreed-upon construction:<br>Claim 4 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component is substantially unionized in a biological environment to which the composition is administered. | |
| **Claim 5** | | |
| 5. The composition of claim 1 wherein the therapeutically active component has increased diffusion through a lipid membrane relative to an identical therapeutically active component in a similar composition the solubility enhancing component. | Agreed-upon construction:<br>Claim 5 includes all the limitations of claim 1, with the additional requirement that the therapeutically active component has increased diffusion through a lipid membrane relative to its diffusion in a similar composition. | |
| **Claim 6** | | |
| 6. The composition of claim 1 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the therapeutically active component relative to the solubility in a biological environment of an identical therapeutically active component in a similar composition without the solubility enhancing component. | Agreed-upon construction:<br>Claim 6 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is effective to solubilize more of the therapeutically active component in a biological environment relative to its solubility in a biological environment without the solubility enhancing component. | |
| **Claim 7** | | |
| 7. The composition of claim 1 wherein said polyanionic component is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic | Agreed-upon construction:<br>Claim 7 includes all the limitations of claim 1, with the additional requirement that the polyanionic component is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic acid, or anionic polymers derived from amino acids and mixtures thereof. | |

| Asserted Claim of '210 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| acid, anionic polymers derived from amino acids and mixtures thereof. | | |
| **Claim 8** | | |
| 8. The composition of claim 1 wherein the solubility enhancing component is selected from the group consisting of anionic cellulose derivatives and mixtures thereof. | Agreed-upon construction:<br>Claim 8 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is selected from the group consisting of anionic cellulose derivatives or a mixtures thereof. | |
| **Claim 9** | | |
| 9. The composition of claim 1 wherein the solubility enhancing component is selected from the group consisting of carboxymethylcelluloses and derivatives thereof. | Agreed-upon construction:<br>Claim 9 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is selected from the group consisting of carboxymethylcelluloses and derivatives thereof. | |
| **Claim 10** | | |
| 10. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.1% (w/v) to about 30% (w/v). | Agreed-upon construction:<br>Claim 10 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is present in the composition in an amount of approximately 0.1% (w/v) to approximately 30% (w/v). | |
| **Claim 11** | | |
| 11. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 10% (w/v). | Agreed-upon construction:<br>Claim 11 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is present in the composition in an amount of approximately 0.2% (w/v) to approximately 10% (w/v). | |
| **Claim 12** | | |
| 12. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v). | Agreed-upon construction:<br>Claim 12 includes all the limitations of claim 1, with the additional requirement that the solubility enhancing component is present in the composition in an amount of approximately 0.2% (w/v) to approximately 0.6% (w/v). | |
| **Claim 13** | | |
| 13. The composition of claim 1 which has a pH of about 7 or greater. | Agreed-upon construction:<br>Claim 13 includes all the limitations of claim 1, with the additional requirement that the pH of the composition is | |

| Asserted Claim of '210 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| | approximately 7 or greater. | |
| **Claim 14** | | |
| 14. The composition of claim 1 which has a pH in a range of about 7 to about 9. | Agreed-upon construction:<br>Claim 14 includes all the limitations of claim 1, with the additional requirement that the pH of the composition is in the range of approximately 7 to approximately 9. | |
| **Claim 15** | | |
| 15. The composition of claim 1 which is ophthalmically acceptable. | Agreed-upon construction:<br>Claim 15 includes all the limitations of claim 1, with the additional requirement that the composition is ophthalmically acceptable. | |
| **Claim 16** | | |
| 16. A therapeutically effective aqueous composition comprising: | Agreed-upon construction:<br>The claim requires a therapeutically effective aqueous composition. | |
| a therapeutically active component selected from the group consisting of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, a salt thereof, and an ester thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered; | Agreed-upon construction:<br>The claimed composition comprises a therapeutically active component, and that component is selected from the group consisting of brimondine, salts of brimonidine, or esters of brimonidine, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient. | |
| and an anionic cellulose derivative in an amount effective to increase the solubility of the therapeutically active component. | Agreed-upon construction:<br>The claimed composition comprises an anionic cellulose derivative, and that anionic cellulose derivative is present in an amount effective to solubilize more of the therapeutically active component. | |
| **Claim 17** | | |
| 17. The composition of claim 16 wherein the alpha-2-adrenergic agonist component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline. | Agreed-upon construction:<br>Claim 17 includes all the limitations of claim 16, with the additional requirement that the alpha-2-adrenergic agonist component comprises brimonidine tartrate. | |
| **Claim 18** | | |
| 18. The composition of claim 16 wherein the anionic cellulose derivative comprises carboxymethylcellulose. | Agreed-upon construction:<br>Claim 18 includes all the limitations of claim 16, with the additional requirement that the anionic cellulose derivative comprises carboxymethylcellulose. | |

| Asserted Claim of '210 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| **Claim 19** | | |
| 19. The composition of claim 16 wherein the anionic cellulose derivative is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v). | Agreed-upon construction:<br>Claim 19 includes all the limitations of claim 16, with the additional requirement that the anionic cellulose derivative is present in an amount in a range of approximately 0.2% (w/v) to approximately 0.6% (w/v). | |
| **Claim 20** | | |
| 20. A therapeutically effective aqueous composition comprising: | Agreed-upon construction:<br>The claim requires a therapeutically effective aqueous composition. | |
| a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered; | Agreed-upon construction:<br>The claimed composition comprises brimonidine tartrate in an amount effective to provide a therapeutic benefit to a patient. | |
| and an anionic solubility enhancing component in an amount effective to increase the solubility of the tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline | Agreed-upon construction:<br>The claimed composition comprises an anionic solubility enhancing component in an amount effective to solubilize more of brimonidine tartrate. | |
| **Claim 21** | | |
| 21. The composition of claim 20 wherein the solubility enhancing component comprises a carboxymethylcellulose. | Agreed-upon construction:<br>Claim 21 includes all the limitations of claim 20, with the additional requirement that solubility enhancing component comprises a carboxymethylcellulose. | |
| **Claim 22** | | |
| 22. The composition of claim 20 which is ophthalmically acceptable. | Agreed-upon construction:<br>Claim 22 includes all the limitations of claim 20, with the additional requirement that the composition is ophthalmically acceptable. | |
| **Claim 23** | | |
| 23. The composition of claim 1 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in | Agreed-upon construction:<br>Claim 23 includes all the limitations of claim 1, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition. | |

| Asserted Claim of '210 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| preserving the composition. | | |
| **Claim 25** | | |
| 25. The composition of claim 23 in which the preservative comprises an oxy-chloro component. | Agreed-upon construction:<br>Claim 25 includes all the limitations of claim 23, with the additional requirement that the preservative comprises an oxy-chloro component. | |
| **Claim 26** | | |
| 26. The composition of claim 23 in which the preservative comprises a chlorite component. | Agreed-upon construction:<br>Claim 26 includes all the limitations of claim 23, with the additional requirement that the preservative comprises a chlorite component. | |
| **Claim 27** | | |
| 27. The composition of claim 16 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition. | Agreed-upon construction:<br>Claim 27 includes all the limitations of claim 16, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition. | |
| **Claim 29** | | |
| 29. The composition of claim 27 in which the preservative comprises an oxy-chloro component. | Agreed-upon construction:<br>Claim 29 includes all the limitations of claim 27, with the additional requirement that the preservative comprises an oxy-chloro component. | |
| **Claim 30** | | |
| 30. The composition of claim 27 in which the preservative comprises a chlorite component. | Agreed-upon construction:<br>Claim 30 includes all the limitations of claim 27, with the additional requirement that the preservative comprises a chlorite component. | |
| **Claim 31** | | |
| 31. The composition of claim 20 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition. | Agreed-upon construction:<br>Claim 31 includes all the limitations of claim 20, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition. | |
| **Claim 33** | | |
| 33. The composition of claim 31 in which the preservative | Agreed-upon construction:<br>Claim 33 includes all the limitations of claim 31, with the | |

| Asserted Claim of '210 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| comprises an oxy-chloro component. | additional requirement that the preservative comprises an oxy-chloro component. | |
| **Claim 34** | | |
| 34. The composition of claim 31 in which the preservative comprises a chlorite component. | Agreed-upon construction:<br>Claim 33 includes all the limitations of claim 31, with the additional requirement that the preservative comprises a chlorite component. | |

**'337 patent**[5]

| Asserted Claim of '337 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| **Claim 1** | | |
| 1. A therapeutically effective ophthalmic composition comprising: | Agreed-upon construction:<br>The claim requires a therapeutically effective ophthalmic composition. | |
| an alpha-2-adrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient in whom the composition is administered; and | Agreed-upon construction:<br>The claimed composition contains an alpha-2-adrenergic agonist component, and that component is present in an amount that is effective to provide a therapeutic benefit to a patient. | |
| a solubility enhancing component other than a cyclodextrin in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component. | Agreed-upon construction:<br>The claimed composition contains a solubility enhancing component, which is a component that enhances the solubility of the alpha-2-adrenergic agonist component, and any solubility enhancing component other than a cylclodextrin is covered by the claim. The solubility enhancing component is present in such an amount that the more of the alpha-2-adrenergic agonist component in the composition is solubilized relative to a similar composition without the solubility enhancing component. | |
| **Claim 2** | | |
| 2. The composition of claim 1 wherein the alpha-2-adrenegic component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, derivatives thereof, and mixtures thereof. | Agreed-upon construction:<br>Claim 2 contains all the limitations of claim 1, with the additional requirement that the alpha-2-adrenergic agonist component is selected from the group consisting of an imino-imidazoline, imidazoline, imidazole, azepine, thiazine, oxazoline, guanidine, catecholamine, derivative thereof, or mixture thereof. | |

[5] Allergan and Apotex agree on the construction of all claim terms of the '337 patent.

| Asserted Claim of '337 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| **Claim 3** | | |
| 3. The composition of claim 1 wherein the therapeutically active component includes a quinoxaline component. | Agreed-upon construction:<br>Claim 3 includes all the limitations of claim 1, with the further requirement that the composition includes a quinoxaline component. | |
| **Claim 4** | | |
| 4. The composition of claim 3 wherein the quinoxaline component is selected from the group consisting of quinoxaline, derivatives thereof, and mixtures thereof. | Agreed-upon construction:<br>Claim 4 includes all the limitations of claim 3, with the further requirement that the quinoxaline component is selected from the group consisting of quinoxaline, derivatives of quinoxaline, or mixtures of quinoxaline. | |
| **Claim 5** | | |
| 5. The composition of claim 1 wherein said solubility enhancing component comprises an anionic polymer. | Agreed-upon construction:<br>Claim 5 includes all the limitations of claim 1, with the further requirement that the solubility enhancing component comprises an anionic polymer. | |
| **Claim 6** | | |
| 6. The composition of claim 1 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological environment of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component. | Agreed-upon construction:<br>Claim 6 includes all the limitations of claim 1, with the further requirement that the solubility enhancing component is effective to solubilize more in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological environment of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component. | |
| **Claim 7** | | |
| 7. The composition of claim 6 wherein the solubility enhancing component comprises an | Agreed-upon construction:<br>Claim 7 includes all the limitations of claim 6, with the further requirement that the solubility enhancing component comprises an anionic polymer. | |

| Asserted Claim of '337 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction |
|---|---|---|
| anionic polymer. | | |
| **Claim 8** | | |
| 8. The composition of claim 3 wherein said solubility enhancing component comprises an anionic polymer. | Agreed-upon construction:<br>Claim 8 includes all the limitations of claim 3, with the further requirement that the solubility enhancing component comprises an anionic polymer. | |
| **Claim 9** | | |
| 9. The composition of claim 1 which further comprises an effective amount of a preservative. | Agreed-upon construction:<br>Claim 9 includes all the limitations of claim 1 with the further requirement that the composition further comprises an effective amount of a preservative. | |
| **Claim 10** | | |
| 10. The composition of claim 6 which further comprises an effective amount of a preservative. | Agreed-upon construction:<br>Claim 10 includes all the limitations of claim 6 with the further requirement that the composition further comprises an effective amount of a preservative. | |

**'834 patent**[6]

| Asserted Claim of '834 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction | Exela's Proposed Construction |
|---|---|---|---|
| **Claim 1** | | | |
| 1. A therapeutically effective aqueous ophthalmic composition comprising: | The claim requires a therapeutically effective aqueous ophthalmic composition.<br><br>*See, e.g.*, '834 patent file history, Reply to office action, dated Mar. 24, 2003. | The claim requires a therapeutically effective aqueous ophthalmic composition.<br><br>*See, e.g.*, '834 patent file history, Reply to office action, dated Mar. 24, 2003. | A water-based formulation containing between 0% and about 0.15% (w/v) of brimonidine tartrate for ophthalmic administration that is demonstrated to provide a therapeutic benefit to a patient to whom the formulation is administered.<br><br>See, e.g., '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Col. 3:23-29, Col. 10:65-Col..11:3. |
| up to about 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate, | The claimed composition comprises up to approximately 0.15% brimonidine tartrate.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).<br><br>*See, e.g.*, '834 patent, Fig. 1; col. 1, lines 33-53; col. 2, lines 48-52; col. 3, lines 23-36; col. 6, lines 8-16; col. 11, lines 1-6; | The claimed composition comprises up to approximately 0.15% brimonidine tartrate.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834). | |

[6] Allergan and Apotex agree on the construction of all claim terms of the '834 patent.

| Asserted Claim of '834 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction | Exela's Proposed Construction |
|---|---|---|---|
| | Example 2; Table IV; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018. | | |
| the composition having a pH of about 7.0 or greater, | The claimed composition has a pH of approximately 7.0 or greater.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).<br><br>*See, e.g.*, '834 patent, Figure 1; col. 4, lines 22-33; col. 11, lines 1-6; Example 2; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018. | The claimed composition has a pH of approximately 7.0 or greater.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834). | The therapeutically effective formulation referred to above has a pH of 7.0 or greater within measurement tolerances. In no event can the claim cover a formulation having a pH of 6.8 or below.<br><br>**pH:** pH is a value taken to represent the acidity or alkalinity of an aqueous solution; it is defined as the logarithm of the reciprocal of the hydrogen-ion concentration of a solution:<br><br>$pH = \log_{10} 1/[H^+]$<br><br>Because the pH scale is logarithmic, the intervals are exponential and thus represent far greater differences in concentration than the values themselves seem to indicate. (Hawley's Condensed Chemical Dictionary, 853- 54 (2001)).<br><br>*See, e.g.*, '834 patent file history, Reply to Office Action, dated Mar. 24, |

| Asserted Claim of '834 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction | Exela's Proposed Construction |
|---|---|---|---|
| | | | 2003.<br><br>During prosecution, applicants disclaimed any pH at or below 6.8 with regard to the - "having a pH of about 7.0 or greater" claim limitation.<br><br>In order to overcome a § 103(a) reference to Burke (U.S. Patent No. 5,215,991) and Beck (U.S. Patent No. 6,358,935), applicant argued that "the present invention is the result of the ***surprising finding*** that increasing the pH of a brimonidine solution to a pH of greater than about 7.0 leads to similar efficacy at a 25% lower concentration (from 0.2% (w/v) to about 0.15% (w/v) or less) ***than is seen in a brimonidine solution at a pH of about 6.6-6.8***."<br><br>*See also* Preliminary Amendment dated Nov. 11, 2002, adding for the first time the limitation "the composition having a pH of about 7.0 or greater"; the specification as filed referred to a pH of about 7 or greater. The use of an additional decimal place (i.e., 7.0) in the |

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| | | | claim signifies to one skilled in the art that the patentee intends precision to at least one decimal place.<br><br>This interpretation is confirmed in the specification in Figure 1, Figure 1 presents solubility data for tests on formulations containing 0.2% brimonidine tartrate. The data shown in Figure 1 is taken from Table IV but omits (and thereby disclaims) all data points for pH values of below 7.0. Specifically excluded are 6.93, 6.68, and 6.67. *See also* Col. 1:32-45; *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995).<br><br>*See also Allergan, Inc. v. Alcon Inc.*, C.A. No. 04-968, 2005 U.S. Dist. LEXIS 32436, at *11 (D. Del. Dec. 8, 2005) ("According to the specification, the claimed compositions enhance the effectiveness of brimonidine tartrate (and other alpha-2-adrenergic agonist components) by increasing its apparent water solubility ***at pHs higher than neutral, or 7.0***") (emphasis added). |

| Asserted Claim of '834 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction | Exela's Proposed Construction |
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| and the 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate being soluble in the composition at about 21° C. | Agreed-upon construction - The brimonidine tartrate is soluble in the composition at approximately 21° C. | | |
| **Claim 2** | | | |
| 2. The composition of claim 1 which includes up to 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate. | Agreed-upon construction - Claim 2 includes all the limitations of claim 1, with the additional requirement that the composition includes up to 0.15% brimonidine tartrate. | | |
| **Claim 3** | | | |
| 3. The composition of claim 1 which includes about 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate. | Agreed-upon construction - Claim 3 includes all the limitations of claim 1, with the additional requirement that the composition includes approximately 0.15% brimonidine tartrate. | | |
| **Claim 4** | | | |
| 4. The composition of claim 1 which included 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate. | Agreed-upon construction - Claim 4 includes all the limitations of claim 1, with the additional requirement that the composition includes 0.15% brimonidine tartrate. | | |
| **Claim 5** | | | |
| 5. The composition of claim 1 having a pH of 7.0 or greater. | Agreed-upon construction: Claim 5 includes all the limitations of claim 1, with the additional requirement that the pH of the composition is 7.0 or greater. | | Not applicable to Exela. |
| **Claim 6** | | | |
| 6. The composition of claim 1 which further comprises a preservative selected from the | Agreed-upon construction - Claim 6 includes all the limitations of claim 1 and further requires that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition. | | |

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| group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition. | | | |
| **Claim 7** | | | |
| 7. The composition of claim 6 wherein the oxy-chloro component comprises a chlorite component. | Agreed-upon construction: Claim 7 includes all the limitations of claim 1 and further requires that the oxy-chloro component comprises a chlorite component. | | Not applicable to Exela. |
| **Claim 8** | | | |
| 8. The composition of claim 1 which is substantially free of anionic cellulosic derivatives. | Agreed-upon construction - Claim 8 includes all the limitations of claim 1 and further requires that the composition be substantially free of anionic cellulosic derivatives. | Not applicable. Allergan did not assert this claim against Apotex. | Agreed-upon construction - Claim 8 includes all the limitations of claim 1 and further requires that the composition be substantially free of anionic cellulosic derivatives. |
| **Claim 9** | | | |
| 9. The composition of claim 1 which is substantially free of carboxymethyl cellulose. | Agreed-upon construction - Claim 9 includes all the limitations of claim 1 and further requires that the composition be substantially free of carboxymethyl cellulose. | Not applicable to Apotex. | Agreed-upon construction - Claim 9 includes all the limitations of claim 1 and further requires that the composition be substantially free of carboxymethyl cellulose. |
| **Claim 10** | | | |
| 10. A therapeutically effective aqueous | The claim requires a therapeutically effective aqueous | The claim requires a therapeutically effective aqueous | A water-based formulation containing |

| Asserted Claim of '834 Patent | Allergan's Proposed Construction | Apotex's Proposed Construction | Exela's Proposed Construction |
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| ophthalmic composition comprising: | ophthalmic composition.<br><br>*See, e.g.*, '834 patent file history, Reply to office action, dated Mar. 24, 2003. | ophthalmic composition.<br><br>*See, e.g.*, '834 patent file history, Reply to office action, dated Mar. 24, 2003. | |
| up to about 0.15% (w/v) of a component selected from the group consisting of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, salts of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, esters of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline and mixtures thereof, | The claimed composition comprises up to approximately 0.15% brimondine, salts of brimonidine, esters of brimonidine, or mixtures of the foregoing.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).<br><br>*See, e.g.*, '834 patent, Fig. 1; col. 1, lines 33-53; col. 2, lines 48-52; col. 3, lines 23-36; col. 6, lines 8-16; col. 11, lines 1-6; Example 2; Table IV; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; | The claimed composition comprises up to approximately 0.15% brimondine, salts of brimonidine, esters of brimonidine, or mixtures of the foregoing.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834). | between 0% and about 0.15% (w/v) of a component selected from the group consisting of: brimonidine; salts of brimonidine; esters of brimonidine; or mixtures thereof, for ophthalmic administration that is demonstrated to provide a therapeutic benefit to a patient to whom the formulation is administered.<br><br>*See* claim 1. |

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| | Application No. 09/904,018. | | |
| the composition having a pH of about 7.0 or greater, | The claimed composition has a pH of approximately 7.0 or greater.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834).<br><br>*See, e.g.*, '834 patent, Figure 1; col. 4, lines 22-33; col. 11, lines 1-6; Example 2; '834 patent file history, Reply to Office Action, dated Mar. 24, 2003; Application No. 09/904,018. | The claimed composition has a pH of approximately 7.0 or greater.<br><br>The ordinary meaning of the term "about" is "approximately." *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Allergan Inc. v. Alcon Inc.*, No. 04-968 (GMS) (D. Del. July 26, 2005) (order construing the terms of U.S. patent nos. 6,673,337 and 6,641,834). | The therapeutically effective formulation referred to in claim 10 having a pH of 7.0 or greater within measurement tolerances. In no event can the claim cover a formulation having a pH of 6.8 or below.<br><br>*See* claim 1. |
| and the component being soluble in the composition at about 21° C. | Agreed-upon construction - The brimonidine tartrate is soluble in the composition at approximately 21° C. | | |

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| **Claim 11** | | | |
| 11. The composition of claim 10 which includes up to 0.15% (w/v) of the component. | Agreed-upon construction - Claim 11 includes all the limitations of claim 10, with the additional requirement that the composition includes up to 0.15% of the brimonidine component. | | |
| **Claim 12** | | | |
| 12. The composition of claim 10 which includes about 0.15% (w/v) of the component | Agreed-upon construction - Claim 12 includes all the limitations of claim 10, with the additional requirement that the composition includes approximately 0.15% of the brimonidine component. | | |
| **Claim 13** | | | |
| 13. The composition of claim 10 which includes 0.15% (w/v) of the component | Agreed-upon construction - Claim 13 includes all the limitations of claim 10, with the additional requirement that the composition includes 0.15% of the brimonidine component. | | |
| **Claim 14** | | | |
| 14. The composition of claim 10 having a pH of 7.0 or greater. | Agreed-upon construction: Claim 14 includes all the limitations of claim 10, with the additional requirement that the pH of the composition is 7.0 or greater. | | Not applicable. |
| **Claim 15** | | | |
| 15. The composition of claim 10, which further comprises an oxy-chloro component in an amount effective to at least assist in preserving the composition. | Agreed-upon construction: Claim 15 includes all the limitations of claim 10, and further requires that the composition further comprises an oxy-chloro component in an amount effective to assist in preserving the composition. | | Not applicable. |
| **Claim 16** | | | |
| 16. The composition of claim 15 wherein the oxy-chloro component comprises a chlorite component. | Agreed-upon to construction: Claim 16 includes all the limitations of claim 15, with the additional requirement that the oxy-chloro component comprises a chlorite component. | | Not applicable. |
| **Claim 17** | | | |
| 17. The composition of claim 10 which is substantially free of anionic cellulosic | Agreed-upon construction - Claim 17 includes all the limitations of claim | Not applicable. | Agreed-upon construction - Claim 17 includes all the limitations of claim 10 |

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| derivatives. | 10 and further requires that the composition be substantially free of anionic cellulosic derivatives. | | and further requires that the composition be substantially free of anionic cellulosic derivatives. |
| **Claim 18** | | | |
| 18. The composition of claim 10 which is substantially free of carboxymethyl cellulose. | Agreed-upon construction - Claim 18 includes all the limitations of claim 10 and further requires that the composition be substantially free of carboxymethyl cellulose. | Not applicable. | Agreed-upon construction - Claim 18 includes all the limitations of claim 10 and further requires that the composition be substantially free of carboxymethyl cellulose. |
| **Claim 20** | | | |
| 20. The composition of claim 10 which further comprises a preservative selected from the group consisting of an oxy-chloro component and a quaternary ammonium compound in an amount effective to at least assist in preserving the composition. | Agreed-upon construction - Claim 20 includes all the limitations of claim 10, with the additional requirement that the composition further comprises either an oxy-chloro or quaternary ammonium preservative in an amount effective to assist in preserving the composition. | | |
| **Claim 22** | | | |
| 22. The composition of claim 20 in which the preservative comprises a oxy-chloro component. | Agreed-upon construction: Claim 22 includes all the limitations of claim 20, with the additional requirement that the preservative comprises an oxy-chloro component. | | Not applicable. |

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Dated: June 3, 2008
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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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